IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
NEWARK DIVISION

MICHAEL BRENNAN	:	
	:	
Plaintiff,	:	
	:	
v.	:	**CIVIL ACTION NO.:**
	:	
C.R. BARD, INC., a New Jersey corporation, BARD PERIPHERAL VASCULAR, INC., (a subsidiary and/or division of defendant C.R. BARD, INC.) an Arizona corporation.	:	**JURY TRIAL DEMANDED**
	:	
Defendants.	:	

COMPLAINT

Plaintiff, Michael Brennan, by and through undersigned attorneys, hereby sues defendants C.R. BARD, INC.; BARD PERIPHERAL VASCULAR, INC., a subsidiary corporation and/or division of C.R. BARD, INC., (collectively, the "Defendants") and allege as follows;

1. This is an action for damages relating to Defendants' development, testing, assembling, manufacturing, packaging, labeling, preparing, distribution, marketing, supplying, and/or selling the defective product sold under the name "inferior vena cava filter" (hereinafter "IVC filter").

PARTIES

2. Michael Brennan ("Plaintiff") at all times relevant to this action resided in, continue to reside in, and are citizens of Henderson, Nevada.

3. Defendant C.R. Bard, Inc. ("Bard") is a corporation duly organized and existing under the laws of the state of Delaware and has its principal place of business at 730 Central Avenue in Murray Hill, New Jersey. Bard at all times relevant to this action, designed, set specifications, manufactured, prepared, compounded, assembled, processed, marketed, distributed, and sold the Denali® Vena Cava Filter system to be implanted in patients throughout the United States, including Nevada. At all times relevant hereto, Defendant Bard was or has been engaged in business in New Jersey, and has conducted substantial business activity in Nevada. Defendant has also carried on solicitations or service activities in the State of New Jersey. Service of Process can be had on Defendant C.R. Bard, Inc. by serving its registered agent, CT Corporation System, at 1999 Bryan Street, Suite 900, Dallas, Texas 75201-3136.

4. Defendant Bard Peripheral Vascular, Inc. ("BPV") is a wholly owned subsidiary corporation of defendant Bard, with its principal place of business at 1625 West 3rd Street, Tempe, Arizona. BPV at all times relevant to this action, designed, set specifications, manufactured, prepared, compounded, assembled,

processed, marketed, distributed, and sold the DENALI® Vena Cava Filter to be implanted in patients throughout the United States, including New Jersey. At all times relevant hereto, Defendant BPV was or has been engaged in business in New Jersey, and has conducted substantial business activity in New Jersey. Defendant has also carried on solicitations or service activities in the State of New Jersey. Service of Process can be had on Defendant Bard Peripheral Vascular, Inc. by serving its registered agent, CT Corporation System, at 3800 North Central Avenue, Suite 460, Phoenix, Arizona 85012.

JURISDICTION AND VENUE

5. Federal diversity jurisdiction in this Court is proper under 28 U.S.C. § 1332 because Plaintiffs are citizens of a different state from the Defendant states of citizenship, and the aggregate amount in controversy exceeds $75,000, exclusive of interest and costs.

6. Venue is proper in this Court under New Jersey Rules of Court 4:3-2(b) because Defendant is actually doing business in New Jersey.

GENERAL FACTUAL ALLEGATIONS

7. Plaintiffs bring this case for serious injuries suffered as a result of a surgically implanted medical device, known as a Denali® Vena Cava Filter System (hereafter Denali Filter), causing serious and ongoing physical, emotional, and economic damages.

8. The DENALI Filter was designed, manufactured, prepared, compounded, assembled, processed, labeled, marketed, distributed, and sold by Defendants from approximately 2013 - present for prevention of blood clots (thrombi) from traveling from the lower portions of the body to the heart and lungs.

9. Prior to Plaintiff, Michael Brennan, being implanted with an DENALI filter around August 2017, Defendants knew and should have known that the device was defective and unreasonably dangerous for, *inter alia*, the following reasons:

a. Defendants failed to conduct any clinical testing, such as animal studies, to determine how the device would function once permanently implanted in the human body.

b. Defendants knew and/or should have known that the Denali Filter and DENALI filter system had a high rate of fracture, migration, and excessive tilting and perforation of the vena cava wall once implanted in the human body. Defendants know and/or should have known that such failures exposed patients to serious injuries, including: death; hemorrhage; cardiac/pericardial tamponade; cardiac arrhythmia and other symptoms similar to myocardial infarction; severe and

persistent pain; perforations of tissue, vessels, and organs; and inability to remove the device. Upon information and belief, Defendants also knew or should have known that certain conditions or post-implant procedures, such as morbid obesity or open abdominal procedures, could affect the safety and integrity of the device. Further, Defendants knew and should have known that these risks for the Denali device and the DENALI filter were and are substantially higher than other similar devices.

c. Further, Defendants knew and/or should have known that the Denali Device and DENALI filter contained conditions, which Defendants did not intend, which resulted in the device not performing as safely as the ordinary customer would expect.

d. Despite being aware of these risks, Defendants misrepresented, omitted, and/or failed to provide adequate warnings of these risks or instructions for safe use.

e. Even when Defendants designed and began marketing what they alleged to be a device that specifically reduced these risks, they still failed to issue a recall or notify consumers that a safer

device was available.

INFERIOR VENA CAVA FILTERS GENERALLY

10. The IVC filter at issue in this case bears the trademark name "DENALI®" filter or "DENALI® Filter System". The DENALI Filter System was manufactured, marketed, and sold by Defendants, C.R. Bard, Inc. and/or Bard Peripheral Vascular, Inc., from 2013 – present.

11. IVC Filters first came on the medical market decades ago. Over the years, several different medical device manufacturers have introduced several different designs of IVC filters.

12. An IVC filter is a device that is designed to filter or "catch" blood clots (called "thrombi") that travel from the lower portions of the body to the heart and lungs. IVC filters may be designed to be implanted, either permanently or temporarily, in the human body, more specifically, within the inferior vena cava.

13. The inferior vena cava is a vein that returns blood to the heart from the lower portions of the body. In certain people, for various reasons, thrombi travel from the vessels in the legs and pelvis, through the vena cava and into the lungs. Oftentimes, these thrombi develop in the deep leg veins. These thrombi are called "deep vein thrombosis" or "DVT". Once thrombi reach the lungs, they are considered "pulmonary emboli" or "PE". Pulmonary emboli present grave risks to human health. They can, and often do, result in death.

14. Certain people are at increased risk for the development of DVT or PE. For instance someone who undergoes knee or hip joint replacement is at risk for developing DVT/PE. Obese patients are also at increased risk for DVT/PE. So too are people who have vascular diseases or whom have experienced previous strokes. A number of other conditions predispose people to develop DVT/PE.

15. Those people at risk for DVT/PE can undergo medical treatment to manage the risk. For example, a doctor may prescribe medications like Heparin, Warfarin, or Lovenox to regulate the clotting factor of the blood. In some people who are at high risk for DVT/PE, or who cannot manage their conditions with medications, physicians may recommend surgically implanting an IVC filter to prevent thromboembolic events.

16. As stated in this Complaint, IVC filters have been on the market for decades. The first IVC filter was introduced in the later 1960's. Since then, the market has been supplemented with all types and designs of filters offered by many different manufacturers.

17. Over the years, a concern developed within the medical community, which was shared with IVC filter manufacturers, that an IVC filter should be designed and manufactured so that it is able to be retrieved from the human body. Ultimately, retrievable IVC filter designs were offered in the market. However, these IVC filter designs were not intended to remain within the human body for

indeterminate periods of time. In other words, the initial designs of retrievable IVC filters were intended to remain implanted for a finite period of time.

WHAT HAPPENS WHEN THE DENALI FILTER SYSTEM FAILS?

18. The failure (fracture and/or migration) of the DENALI Filter System leads to a number of different, and potentially fatal, complications. These complications include, but are not limited to:

a. Death;

b. Hemorrhage;

c. Cardiac/pericardial tamponade (pressure caused by a collection of blood in the area around the heart);

d. Severe and persistent pain; and,

e. Perforation of tissue, vessels and organs.

19. The person who experiences failure (fracture and/or migration) of the DENALI Filter System typically experiences an acute onset of chest pain and shortness of breath. This typically results in the person presenting to an emergency room, hospital, and/or physician for evaluation.

THE CASE FOR MEDICAL MONITORING

20. In certain cases, medical monitoring is required to evaluate whether a DENALI Filter System (or portions of the DENALI Filter) has fractured, tilted and/or migrated (collectively referred to herein as "device failure" or "failure"). In

order to determine whether failure of the DENALI Filter System has occurred, imaging studies must be performed. Typically, these imaging studies will include un-enhanced computed tomography scan (CT scan) so that the filter may be visualized. CT scan imaging produces an image of the filter and is able to reveal whether the filter has fractured or migrated.

21. Patients requiring medical monitoring are recommended [1] to undergo regular and frequent imaging studies of the device or portions of the device at least once or twice annually. As long as the device, or portions of the device, remains within the body of the patient, the potential for future device failure exists. Consequently, these patients require regular and frequent medical monitoring for the duration of time the device, or portions of the device, remain within their bodies.

22. Patients eligible for medical monitoring for the DENALI Filter System or portions of the device need not have experienced past failure of the DENALI Filter System. For example, patients who have undergone implant of the DENALI Filter System frequently learn that the DENALI Filter System cannot be

[1] Research studies performed in 2008 call for the need of regular and frequent medical monitoring for a patient who had the Denali vena cava filter implanted in their body. This 2008 research study performed by Jeffrey Hull, M.D. recommends regular and frequent monitoring of patients in whom the Denali Filter System remains implanted. (*Retrieval of the Denali Filter after Arm Perforation, Fracture, and Migration to the Right Ventricle*, Hull *et. al*., J. Vasc. Intern. Radiol. 2008; 19:1107.1111). Dr. Hull specifically recommends "imaging with un-enhanced abdominal CT to look for arm perforation, fracture, or migration to further evaluate the scope and risk posed by this [the Denali] filter."

removed due to the fact that it has "grown into" tissue, but, the fracture, tilt or migration of the device may not yet have occurred. As a result of the inability to remove the DENALI Filter System, the device must remain permanently implanted in the patient, for the patient's lifetime. Although these patients may not yet have experienced device failure, they are at risk for future device failure and require regular and frequent monitoring to evaluate the integrity of the DENALI Filter System. In addition to the aforementioned imaging studies, endovascular intervention (typically cardiac catheterization) may also be used by medical professionals to diagnose or discover whether fractured portions of the DENALI Filter System have migrated to the heart or lungs. Furthermore, endovascular surgery may assess the nature and extent of the damage resulting from failure of the DENALI Filter System.

23. In those instances where device fracture has occurred, and depending on the circumstances particular to the patient, a person may be required to undergo one or all of the following medical procedures:

a. CT scanning or other imaging studies;

b. Cardiac catheterization;

c. Open heart surgery; and/or,

d. Removal of the DENALI Filter System from the vena cava.

24. The DENALI Filter System was placed in Plaintiff, Michael Brennan's body on or about August of 2017. Plaintiff learned on or about November 2018 that his DENALI Filter System had caused his injuries. The Plaintiff did not and could not have discovered his injury, the cause of his injury, nor the Defendants part in the cause of his injury until November 2018, at the earliest. Plaintiff has incurred significant medical expenses and has endured extreme pain and suffering, loss of enjoyment of life, and other losses, some of which are permanent in nature. As a result of the failure of the DENALI Filter System, Plaintiff has become impaired and his ability to earn wages has been diminished, and will remain so in the future.

25. As a direct and proximate result of the conduct and defective product of the Defendants, C.R. Bard, Inc. and Bard Peripheral Vascular, Inc., as alleged in his Complaint, Plaintiff has suffered permanent and continuing injury, loss of enjoyment of life, pain, suffering, and impairment. Plaintiff has suffered emotional trauma, harm and injuries. Plaintiff's ability to carry on the affairs of his daily life has been impacted and diminished, and will continue to diminish in the future.

26. As a direct and proximate result of the conduct and defective product of the Defendants, C.R. Bard, Inc. and Bard Peripheral Vascular, Inc., as alleged in this Complaint, the Plaintiff has incurred substantial medical expenses, and will continue to incur substantial medical expenses into the future.

THE NECESSITY FOR MEDICAL MONITORING

27. As a direct and proximate result of the conduct and defective product of the Defendants, C.R. Bard, Inc. and Bard Peripheral Vascular, Inc., as alleged in this Complaint, medical monitoring is necessary for Plaintiff. Medical monitoring includes:

a. Regularly scheduled CT scans or other appropriate imaging studies; and/or,

b. Potential cardiac catheterization or other endovascular procedure to detect the presence of migrated pieces of the DENALI Filter System; and/or physicians' visits and examinations.

THE DEFENDANTS' KNOWLEDGE OF THE FAILURE OF THE DENALI FILTER SYSTEM AND THE DANGERS ASSOCIATED WITH THE DEVICE

28. Upon information and belief, Plaintiff allege that as early as 2013, the Defendants C.R. Bard, Inc. and Bard Peripheral Vascular, Inc. were aware and had knowledge of the fact that the DENALI Filter System was defective and unreasonably dangerous and was causing injury and death to patients who had received the DENALI Filter System.

29. Upon information and belief, from the time the DENALI Filter System became available on the market, the Defendants, C.R. Bard, Inc. and Bard

Peripheral Vascular, Inc., embarked on an aggressive campaign of "off-label marketing" concerning the DENALI Filter System.

30. The conduct of the Defendants C.R. Bard, Inc. and Bard Peripheral Vascular, Inc. as alleged in this Complaint, constituted, willful, wanton, gross, and outrageous corporate conduct that demonstrates a conscious disregard for the safety of Plaintiff Michael Brennan. The Defendants C.R. Bard, Inc. and Bard Peripheral Vascular Inc. had actual knowledge of dangers to the life and limb of the Plaintiff presented by the DENALI Filter System, yet consciously failed to act reasonably to:

a. Inform or warn the Plaintiff, his physicians, or the public at large of the dangers; and

b. Recall the DENALI System from the market in a timely and safe fashion.

31. Despite having knowledge as early as 2013 of the unreasonably dangerous and defective nature of the product, the Defendants C.R. Bard, Inc. and Bard Peripheral Vascular, Inc. consciously disregarded the known risks and continued to actively market and offer for sale the DENALI Filter System.

32. Plaintiff further allege that the Defendants C.R. Bard, Inc. and Bard Peripheral Vascular, Inc. acted in willful, wanton, gross manner, and in total

disregard for the health and safety of the users or consumers of its DENALI Filter System, including Plaintiff Michael Brennan, and acted to serve their own interests and having reason to know and consciously pursued a course of conduct knowing that such conduct created a substantial risk of significant harm to other persons. Therefore, Defendants C.R. Bard, Inc. and Bard Peripheral Vascular, Inc. should be required to respond to the Plaintiff in the form of a punitive or exemplary damage award.

THE FEDERAL REQUIREMENTS

33. Federal regulation states that "recall means a firm's removal or correction of a marketed product that the Food and Drug Administration considers to be in violation of the laws it administers and against which the agency would initiate legal action, e.g. seizure." See 21 CFR §7.3(g).

34. Federal regulation states that "recall classification means the numerical designation, i.e., I, II or III, assigned by the Food and Drug Administration to a particular product recall to indicate the relative degree of health hazard presented by the product being recalled." See 21 CFR §7.3(m).

35. Federal regulation states that "class II is a situation in which use of, or exposure to, a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote." See 21 CFR §7.3(m).

36. The classification of the product withdrawals and corrections of the Defendants' devices (described above) as Class II Recalls by the F.D.A confirms by definition that the devices were in violation of federal law and that initiation of legal action or seizure would be indicated for these devices.

37. Pursuant to federal law, a device is deemed to be adulterated if, among other things, it fails to meet established performance standards, or if the methods, facilities or controls used for its manufacture, packing, storage or installation are not in conformity with federal requirements. See 21 U.S.C. §351.

38. Pursuant to federal law, a device is deemed to be misbranded if, among other things, its labeling is false or misleading in any particular manner, or if it is dangerous to health when used in the manner prescribed, recommended or suggested in the labeling thereof. See 21 U.S.C. §352.

39. Pursuant to federal law, manufacturers are required to comply with F.D.A. regulation of medical devices, including F.D.A. requirements for records and reports, in order to prohibit introduction of medical devices that are adulterated or misbranded, and to assure the safety and effectiveness of medical devices. In particular, manufacturers must keep records and make reports if any medical device that may have caused or contributed to death or serious injury, or if the device has malfunctioned in a manner likely to cause or contribute to death or serious injury. Federal law also mandates that the F.D.A. establish regulations

requiring a manufacturer of a medical device to report promptly to F.D.A. any correction or removal of a device undertaken to reduce a risk to health posed by the device, or to remedy a violation of federal law by which a device may present a risk to health. See 21 U.S.C. §360(i).

40. Pursuant to federal law, the Secretary of Health and Human Services may prescribe regulations requiring that the methods used in, and that facilities and controls used for, the manufacture, pre-production design validation (including a process to assess the performance of a device but not including an evaluation of the safety or effectiveness of a device), packaging, storage, and installation of a device conform to current good manufacturing proactive, as prescribed in such regulations, to assure that the device will be safe and effective and otherwise in compliance with federal law. See 21. U.S.C §360j (f).

41. Pursuant to F.D.A. regulation, adverse events associated with a medical device must be reported to F.D.A. within 30 days after the manufacturer becomes aware that a device may have caused or contributed to death or serious injury, or that a device has malfunctioned and would be likely to cause or contribute to death or serious injury if the malfunction was to recur. Such reports must contain all information reasonably known to the manufacturer, including any information that can be obtained by analysis, testing, or other evaluation of the device, and any information in the manufacturer's possession. In addition,

manufacturers are responsible for conducting an investigation of each adverse event, and must evaluate the cause of the adverse event. See 21 CFR §803.50.

42. Pursuant to federal regulation, manufacturers of medical devices must also describe in every individual adverse event report whether remedial action was taken in regard to the adverse event, and whether the remedial action was reported to F.D.A. as a removal or correction of the device. See 21 CFR §803.52.

43. Pursuant to federal regulation, manufacturers must report to F.D.A. within five (5) business days after becoming aware of any reportable MDR event or events, including a trend analysis that necessitates remedial action to prevent an unreasonable risk of substantial harm to the public health. See 21 CFR §803.53.

44. Pursuant to federal regulation, device manufacturers must report promptly to F.D.A. any device corrections and removals, and maintain records of device corrections and removals. F.D.A. regulations require submission of a written report within ten (10) working days of any correction or removal of a device initiated by the manufacturer to reduce a risk to health posed by the device, or to remedy a violation of the Act caused by the device, which may present a risk to health. The written submission must contain, among other things, a description of the event giving rise to the information reported and the corrective or removal actions taken, and any illness or injuries that have occurred with use of the device, including reference to any device report numbers. Manufacturers must also

indicate the total number of devices manufactured or distributed which are subject to the correction or removal, and provide a copy of all communications regarding the correction or removal. See 21 CFR §806.

45. Pursuant to federal regulation, manufacturers must comply with specific quality system requirements promulgated by F.D.A. These regulations require manufacturers to meet design control requirements, including but not limited to, conducting design validation to ensure that devices conform to defined user needs and intended uses. Manufacturers must also meet quality standards in manufacture and production. Manufacturers must establish and maintain procedures for implementing corrective actions and preventive actions, and investigate the cause of nonconforming products and take corrective action to prevent recurrence. Manufacturers are also required to review and evaluate all complaints and determine whether an investigation is necessary. Manufacturers are also required to use statistical techniques where necessary to evaluate product performance. See 21 CFR §820.

46. The regulations requiring conformance to good manufacturing practices are set forth in 21 CFR §820 *et seq*. As explained in the Federal Register, because the Current Good Manufacturing Practice (CGMP) regulations must apply to a variety of medical devices, the regulations do not prescribe the details for how a manufacturer must produce a device. Rather, the quality system regulations

provide a framework of basic requirements for each manufacturer to use in establishing a quality system appropriate to the devices designed and manufactured, and the manufacturing processes employed. Manufacturers must adopt current and effective methods and procedures for each device they design and manufacture to comply with and implement the basic requirements set forth in the quality system regulations.

47. Pursuant to 21 CFR §820.1I, the failure to comply with any applicable provision in Part 820 renders a device adulterated under section 501(h) of the Federal Food Drug & Cosmetic Act ("the Act") (21 U.S.C. § 351).

48. Pursuant to 21 CFR §820.5, each manufacturer shall establish and maintain a quality system that is appropriate for the specific medical device designed or manufactured. "Quality system" means the organizations structure, responsibilities, procedures, processes, and resources for implementing quality management. See 21 CFR §820.3(v).

49. Pursuant to 21 CFR §820.22, each manufacturer shall establish procedures for quality audits and conduct such audits to assure that the quality system is in compliance with the established quality system requirements and to determine the effectiveness of the quality system.

50. Pursuant to 21 CFR §820.30(a), each manufacturer shall establish and maintain procedures to control the design of the device in order to ensure that

specified design requirements are met.

51. Pursuant to 21 CFR §820.30(d), each manufacturer shall establish and maintain procedures for defining and documenting design output in terms that allow an adequate evaluation of conformance to design input requirements.

52. Pursuant to 21 CFR §820.30I, each manufacturer shall establish and maintain procedures to ensure that formal documented reviews of the design results are planned and conducted at appropriate stages of the device's design development.

53. Pursuant to 21 CFR §820.30(f), each manufacturer shall establish and maintain procedures for verifying the device design to confirm that the device design output meets the design input requirements.

54. Pursuant to 21 CFR §820.30(g), each manufacturer shall establish and maintain procedures for validating the device design. Design validation shall be performed under defined operating conditions on initial production units, lots, or batches, or their equivalents. Design validations shall ensure that devices conform to defined user needs and intended uses and shall include testing of production units under actual or simulated use conditions.

55. Pursuant to 21 CFR §820.30(h), each manufacturer shall establish and maintain procedures to ensure that the device design is correctly translated into production specifications.

56. Pursuant to 21 CFR §820.30(i), each manufacturer shall establish and maintain procedures for the identification, documentation, validation or where appropriate verification, review, and approval of design changes before their implementation.

57. Pursuant to 21 CFR §820.70(a), each manufacturer shall develop, conduct, control, and monitor production processes to ensure that a device conforms to its specifications. Where deviations from device specifications could occur as a result of the manufacturing process, the manufacturer shall establish and maintain process control procedures that describe any process controls necessary to ensure conformance to specifications. Such process controls shall include:

d. Documented instructions, standard operating procedures (SOP's), and methods that define and control the manner of production;

b. Monitoring and control of process parameters and component and device characteristics during production;

c. Compliance with specified reference standards or codes;

d. The approval of processes and process equipment; and

e. Criteria for workmanship which shall be expressed in documented standards or by means of identified and approved representative samples.

58. Pursuant to 21 CFR §820.70(b), each manufacturer shall establish and maintain procedures for changes to a specification, method, process, or procedure.

59. Pursuant to 21 CFR §820.70I, each manufacturer shall establish and maintain procedures to adequately control environmental conditions that could reasonably be expected to have an adverse effect on product quality, including periodic inspection of environmental control system(s) to verify that the system, including necessary equipment, is adequate and functioning properly.

60. Pursuant to 21 CFR §820.70I, each manufacturer shall establish and maintain procedures to prevent contamination of equipment or product by substances that could reasonably be expected to have an adverse effect on product quality.

61. Pursuant to 21 CFR §820.70(g), each manufacturer shall ensure that all equipment used in the manufacturing process meets specified requirement and is appropriately designed, constructed, placed, and installed to facilitate maintenance, adjustment, cleaning and use.

63. Pursuant to 21 CFR §820.70(h), each manufacturer shall establish and maintain procedures for the use and removal of manufacturing material which could reasonably be expected to have an adverse effect on product quality to ensure that it is removed or limited to an amount that does not adversely affect the

device's quality.

64. Pursuant to 21 CFR §820.70(i), when computers or automated data processing systems are used as part of production or the quality system, the manufacturer shall validate computer software for its intended use according to an established protocol.

65. Pursuant to 21 CFR §820.72, each manufacturer shall ensure that all inspection, measuring, and test equipment, including mechanical, automated, or electronic inspection and test equipment, is suitable for its intended purposes and is capable of producing valid results. Each manufacturer shall establish and maintain procedures to ensure that equipment is routinely calibrated, inspected, checked, and maintained.

66. Pursuant to 21 CFR §820.75(a), where the results of a process cannot be fully verified by subsequent inspection and test, the process shall be validated with a high degree of assurance and approved according to established procedures. "Process validation" means establishing by objective evidence that a process consistently produces a result or product meeting its predetermined specifications. See 21 CFR §820.3(z) (1).

67. Pursuant to 21 CFR §820.75(b), each manufacturer shall establish and maintain procedures for monitoring and control of process parameters for

validated processes to ensure that the specified requirements continue to be met. Each manufacturer shall ensure that validated processes are performed by qualified individuals.

68. Pursuant to 21 CFR §820.90, each manufacturer shall establish and maintain procedures to control product that does not conform to specified requirements.

69. Pursuant to 21 CFR §820.100, each manufacturer shall establish and maintain procedures for implementing corrective and preventive action. The procedures shall include requirements for:

d. Analyzing processes, work operations, concessions, quality audit reports, quality records, service records, complaints, returned product, and other sources of quality data to identify existing and potential causes of nonconforming product, or other quality problem,

b. Investigating the cause of nonconformities relating to product, processes and the quality system;

c. Identifying the action(s) needed to correct and prevent recurrence of nonconforming product and other quality problems;

d. Verifying or validating the corrective and preventative action to ensure that such action is effective and does not adversely affect the finished device;

e. Implementing and recording changes in methods and procedures needed to correct and prevent identified quality problems;

f. Ensuring that information related to quality problems or nonconforming product is disseminated to those directly responsible for assuring the quality of such product or the prevention of such problems; and

g. Submitting relevant information on identified quality problems, as well as corrective and preventative actions, for management review.

DEFENDANTS' DENALI FILTER SYSTEM IS A 510(k) APPROVED MEDICAL DEVICE

70. Defendants submitted a §510(k) premarket notification and obtained marketing clearance for its DENALI Filter System from the F.D.A. under Section 510(k) of the Act. *See* 21 U.S.C. §360 *et seq.*

80. Under the §510(k) approval process, the F.D.A. determined that

Defendants' DENALI Filter System was "substantially equivalent" to devices that have been reclassified in accordance with the provisions of the Act and did not require F.D.A. approval of a pre-market approval application (PMA).

81. Upon information and belief, Defendants' DENALI Filter System is adulterated pursuant to 21 U.S.C. §351 because, among other things, it failed to meet established performance standards, and/or the methods, facilities, or controls used for its manufacture, packing, storage or installation are not in conformity with federal requirements. *See* 21 U.S.C. §351.

82. Upon information and belief, Defendants' DENALI Filter System is misbranded because, among other things, it is dangerous to health when used in the manner prescribed, recommended or suggested in the labeling thereof. *See* 21U.S.C. §352.

83. Upon information and belief, Defendants' DENALI Filter System is adulterated pursuant to 21 U.S.C. §351 because Defendants failed to establish and maintain CGMP for their DENALI Filter System in accordance with 21 CFR §820 *et seq.*, as set forth above.

84. Upon information and belief, Defendants failed to establish and maintain CGMP with respect to the quality audits, quality testing and process validation for their DENALI Filter System.

85. As a result of Defendants' failure to establish and maintain CGMP as

set forth above, Defendants' DENALI Filter System was defective and failed, resulting in injuries to the Plaintiff.

86. If Defendants had complied with the federal requirements regarding CGMP, Defendants' DENALI Filter System would have been manufactured properly such that it would not have resulted in injuries to the Plaintiff.

FRAUDULENT CONCEALMENT

87. Any applicable statutes of limitation have been tolled by the knowing and active concealment and denial of material facts known by Defendants when they had a duty to disclose those facts. They have kept Plaintiff ignorant of vital information essential to the pursuit of her claims, without any fault or lack of diligence on Plaintiff's part, for the purpose of obtaining delay on Plaintiff's part in filing on their causes of action. Defendants' fraudulent concealment did result in such delay.

88. Defendants are estopped from relying on the statute of limitations defense because Defendants failed to timely disclose, among other things, facts evidencing the defective and unreasonably dangerous nature of the DENALI Filter Systems.

89. The Defendants are and were under a continuing duty to disclose the true character, quality and nature of the device that was implanted in Plaintiff, but instead they concealed them. Defendants' conduct, as described in this complaint,

amounts to conduct purposely committed, which Defendants must have realized was dangerous, heedless and reckless, without regard to the consequences or the rights and safety of Plaintiff.

CORPORATE/VICARIOUS LIABILITY

90. At all times herein mentioned, each of the Defendants was the agent, servant, partner, aider and abettor, co-conspirator and/or joint venture of each of the other Defendants herein and was at all times operating and acting within the purpose and scope of said agency, service, employment, partnership, conspiracy and/or joint venture and rendered substantial assistance and encouragement to the other Defendants, knowing that their collective conduct constituted a breach of duty owed to the Plaintiff.

91. There exists and, at all times herein mentioned, there existed a unity of interest in ownership between certain Defendants and other certain Defendants such that any individuality and separateness between the certain Defendants has ceased and these Defendants are the alter ego of the other certain Defendants and exerted control over those Defendants. Adherence to the fiction of the separate existence of these certain Defendants as entities distinct from other certain Defendants will permit an abuse of the corporate privilege and would sanction a fraud and/or would promote injustice.

92. At all times herein mentioned, each Defendant was engaged in the

business of, or were successors in interest to, entities engaged in the business of researching, designing, formulating, compounding, testing, manufacturing, producing, processing, assembling, inspecting, distributing, marketing, labeling, promoting, packaging, prescribing and/or advertising for sale, and selling products for use by the Plaintiff. As such, each Defendant is individually, as well as jointly and severally, liable to the Plaintiff for Plaintiff's damages.

93. At all times herein mentioned, the officers and/or directors of the Defendants named herein participated in, authorized and/or directed the production and promotion of the aforementioned products when they knew, or with the exercise of reasonable care and diligence should have known, of the hazards and dangerous propensities of said products, and thereby actively participated in the tortious conduct that resulted in the injuries suffered by the Plaintiff.

FIRST CAUSE OF ACTION
NEGLIGENCE

94. Plaintiff re-alleges and incorporates by reference each and every allegation contained in the foregoing paragraphs as though fully set forth herein.

95. At all times relevant to this cause of action, the Defendants Bard and BPV were in the business of designing, developing, setting specifications, manufacturing, marketing, selling, and distributing the DENALI Filters.

96. Defendants designed, manufactured, marketed, inspected, labeled,

promoted, distributed and sold the DENALI Filter that was implanted in Plaintiff Michael Brennan.

97. Defendants had a duty to exercise reasonable and prudent care in the development, testing, design, manufacture, inspection, marketing, labeling, promotion, distribution and sale of the DENALI Filter so as to avoid exposing others to foreseeable and unreasonable risks of harm.

98. Defendants knew or reasonably should have known that the DENALI Filter was dangerous or was likely to be dangerous when used in its intended or reasonably foreseeable manner.

99. At the time of manufacture and sale of the DENALI Filter, Defendants knew or should have known that the DENALI Filter:

a. Was designed and manufactured in such a manner so as to present an unreasonable risk of fracture of portions of the device;

b. Was designed and manufactured so as to present an unreasonable risk of migration of the device and/or portions of the device;

c. Was designed and manufactured so as to present an unreasonable risk of the device tilting and/or perforating the vena cava wall; and/or,

d. Was designed and manufactured to have unreasonable and insufficient strength or structural integrity to withstand normal placement within the human body.

100. At the time of manufacture and sale of the DENALI Filter, Defendants knew or should have known that using the DENALI Filter in its intended use or in a reasonably foreseeable manner created a significant risk of a patient suffering severe health side effects, including, but not limited to: hemorrhage; cardiac/pericardial tamponade; cardiac arrhythmia and other symptoms similar to myocardial infarction; perforations of tissue, vessels and organs; and other severe personal injuries and diseases, which are permanent in nature, including, but not limited to, death, physical pain and mental anguish, scarring and disfigurement, diminished enjoyment of life, continued medical care and treatment due to chronic injuries/illness proximately caused by the device; and the continued risk of requiring additional medical and surgical procedures including general anesthesia, with attendant risk of life threatening complications.

101. Defendants knew or reasonably should have known that consumers of the DENALI Filter would not realize the danger associated with using the device in its intended use and/or in a reasonably foreseeable manner.

102. Defendants breached their duty to exercise reasonable and prudent care in the development, testing, design, manufacture, inspection, marketing,

labeling, promotion, distribution and sale of the DENALI Filter in, among other ways, the following acts and omissions:

d. Designing and distributing a product in which they knew or should have known that the likelihood and severity of potential harm from the product exceeded the burden of taking safety measures to reduce or avoid harm;

b. Designing and distributing a product in which they knew or should have known that the likelihood and severity of potential harm from the product exceeded the likelihood of potential harm from other device available for the same purpose;

c. Failing to use reasonable care in manufacturing the product and producing a product that differed from their design or specifications or from other typical units from the same production line;

d. Failing to use reasonable care to warn or instruct, including pre and post-sale, Plaintiff Michael Brennan, Plaintiff's physicians, or the general health care community about the DENALI Filter's substantially dangerous condition or about facts making the product likely to be dangerous;

e. Failing to perform reasonable pre- and post-market testing of

the DENALI Filter to determine whether or not the product was safe for its intended use;

f. Failing to provide adequate instructions, guidelines, and safety precautions, including pre- and post-sale, to those persons to whom it was reasonably foreseeable would prescribe, use, and implant the DENALI Filter;

g. Advertising, marketing and recommending the use of the DENALI Filter, while concealing and failing to disclose or warn of the dangers known by Defendants to be connected with and inherent in the use of the DENALI Filter;

h. Representing that the DENALI Filter was safe for its intended use when in fact, Defendants knew and should have known the product was not safe for its intended purpose;

i. Continuing manufacture and sale of the DENALI Filter with the knowledge that said product was dangerous and not reasonably safe, and failing to comply with FDA good manufacturing regulations;

j. Failing to use reasonable and prudent care in the design,

research, manufacture, and development of the DENALI Filter so as to avoid the risk of serious harm associated with the use of the DENALI Filter;

k. Advertising, marketing, promoting and selling DENALI Filter for uses other than as approved and indicated in the product's label;

l. Failing to establish an adequate quality assurance program used in the manufacturing of the DENALI Filter; and,

m. Failing to establish and maintain an adequate post-market surveillance program.

103. A reasonable manufacturer, distributor, or seller under the same or similar circumstances would not have engaged in the before-mentioned acts and omissions.

104. As a direct and proximate result of the foregoing negligent acts and omissions by Defendants, Plaintiff has suffered and will continue to suffer serious physical injuries, economic loss, loss of enjoyment of life, disability, and other losses, in an amount to be determined at trial.

SECOND CAUSE OF ACTION
STRICT PRODUCTS LIABILITY – FAILURE TO WARN

105. Plaintiff re-alleges and incorporates by reference each and every allegation contained in the foregoing paragraphs as though fully set forth herein.

106. Defendants designed, set specifications, manufactured, prepared, compounded, assembled, processed, marketed, labeled, distributed, and sold the DENALI Filter, including the one implanted into Plaintiff Michael Brennan, into the stream of commerce and in the course of same, directly advertised and marketed the device to consumers or persons responsible for consumers.

107. At the time Defendants designed, manufactured, prepared, compounded, assembled, processed, marketed, labeled, distributed, and sold the device into the stream of commerce, Defendants knew or should have known the device presented an unreasonable danger to users of the product when put to its intended and reasonably anticipated use. Specifically, Defendants knew or should have known at the time they manufactured, labeled, distributed and sold the DENALI Filter, which was implanted in Plaintiff Michael Brennan, that the DENALI Filter, *inter alia*, posed a significant and higher risk than other similar devices of device failure (fracture, migration, tilting, and perforation of the vena cava wall) and resulting serious injuries. Upon information and belief, Defendants also knew or should have known that certain conditions or post-implant procedures, such as morbid obesity or open abdominal procedures, could affect the safety and integrity of the device.

108. Therefore, Defendants had a duty to warn of the risk of harm associated with the use of the device and to provide adequate instructions on the

safe and proper use of the device. Defendants further had a duty to warn of dangers and proper safety instructions that it became aware of even after the device was distributed and implanted in Plaintiff Michael Brennan.

109. Despite this duty, Defendants failed to adequately warn of material facts regarding the safety and efficacy of the DENALI Filter, and further failed to adequately provide instructions on the safe and proper use of the device.

110. No health care provider, including Plaintiff's, or patient would have used the device in the manner directed, had those facts been made known to the prescribing healthcare providers and/or ultimate users of the device.

111. The health risks associated with the device as described herein are of such a nature that ordinary consumers would not have readily recognized the potential harm.

112. Plaintiff and Plaintiff's health care providers used the device in a normal, customary, intended, and foreseeable manner, namely as a surgically implanted device used to prevent pulmonary embolisms.

113. Therefore, the DENALI Filter implanted in Plaintiff was defective and unreasonably dangerous at the time of release into the stream of commerce due to inadequate warnings, labeling and/or instructions accompanying the product.

114. The DENALI Filter implanted in Plaintiff was in the same condition as when it was manufactured, inspected, marketed, labeled, promoted, distributed and sold by Defendants.

115. As a direct and proximate result of Defendants' lack of sufficient warning and/or instructions, Plaintiff has suffered and will continue to suffer serious physical injuries, economic loss, loss of enjoyment of life, disability, and other losses, in an amount to be determined at trial.

THIRD CAUSE OF ACTION
STRICT PRODUCTS LIABILITY – DESIGN DEFECTS

116. Plaintiff re-alleges and incorporates by reference each and every allegation contained in the foregoing paragraphs as though fully set forth herein.

117. At all times relevant to this action, Defendants developed, tested, designed, manufactured, inspected, labeled, promoted, distributed and sold into the stream of commerce the DENALI Filter, including the one implanted in Plaintiff.

118. The DENALI Filter was expected to, and did, reach its intended consumers without substantial change in the condition in which it was in when it left Defendants' possession. In the alternative, any changes that were made to DENALI Filter implanted in Plaintiff were reasonably foreseeable to Defendants.

119. The DENALI Filter implanted in Plaintiff was defective in design because it failed to perform as safely as persons who ordinarily use the product would have expected at the time of use.

120. The DENALI Filter implanted in Plaintiff was defective in design, in that its risks of harm exceeded its claimed benefits.

121. Plaintiff and Plaintiff's health care providers used the DENALI Filter in a manner that was reasonably foreseeable to Defendants.

122. Neither Plaintiff, nor Plaintiff's health care providers could have, by the exercise of reasonable care, discovered the devices defective condition or perceived its unreasonable dangers prior to Plaintiff's implantation with the device.

123. As a direct and proximate result of the DENALI Filter's defective design, Plaintiff has suffered and will continue to suffer serious physical injuries, economic loss, loss of enjoyment of life, disability, and other losses, in an amount to be determined at trial.

FOURTH CAUSE OF ACTION
STRICT PRODUCTS LIABILITY – MANUFACTURING DEFECT

124. Plaintiff re-alleges and incorporates by reference each and every allegation contained in the foregoing paragraphs as though fully set forth herein.

125. Defendants designed, set specifications, manufactured, prepared, compounded, assembled, processed, marketed, labeled, distributed, and sold the DENALI Filter that was implanted into Plaintiff.

126. The DENALI Filter implanted in Plaintiff contained a condition, which Defendants did not intend, at the time it left Defendants' control and possession.

127. Plaintiff and Plaintiff's health care providers used the device in a manner that was reasonably foreseeable to Defendants.

128. As a result of this condition, the product injured Plaintiff and failed to perform as safely as the ordinary consumer would expect when used in a reasonably foreseeable manner.

129. As a direct and proximate result of the DENALI Filter's manufacturing defect, Plaintiff has suffered and will continue to suffer serious physical injuries, economic loss, loss of enjoyment of life, disability, and other losses, in an amount to be determined at trial.

FIFTH CAUSE OF ACTION
BREACH OF IMPLIED WARRANTY OF MERCHANTABILITY

130. Plaintiff re-alleges and incorporates by reference each and every allegation contained in the foregoing paragraphs as though fully set forth herein.

131. At all times relevant to this action, Defendants designed, researched, developed, manufactured, tested, labeled, inspected, advertised, promoted, marketed, sold, and distributed into the stream of commerce the DENALI Filter for use as a surgically implanted device used to prevent pulmonary embolisms and for uses other than as approved and indicated in the product's instructions, warnings, and labels.

132. At the time and place of the sale, distribution, and supply of the

Defendants' DENALI Filter System to Plaintiff by way of Plaintiff's health care providers and medical facilities, Defendants expressly represented and warranted, by labeling materials submitted with the product, that the DENALI Filter System was safe and effective for its intended and reasonably foreseeable use.

133. Defendants knew of the intended and reasonably foreseeable use of the DENALI Filter, at the time they marketed, sold, and distributed the product for use by Plaintiff, and impliedly warranted the product to be of merchantable quality, and safe and fit for its intended use.

134. Defendants impliedly represented and warranted to the healthcare community, Plaintiff and Plaintiff's health care providers, that the DENALI Filter was safe and of merchantable quality and fit for the ordinary purpose for which the product was intended and marketed to be used.

135. The representations and implied warranties made by Defendants were false, misleading, and inaccurate because the DENALI Filter was defective, unsafe, unreasonably dangerous, and not of merchantable quality, when used in its intended and/or reasonably foreseeable manner. Specifically, at the time of Plaintiff's purchase of the DENALI Filter from the Defendants, through Plaintiff's physicians and medical facilities, it was not in a merchantable condition in that:

d. It was designed in such a manner so as to be prone to a statistically high incidence of failure, including fracture,

migration, excessive tilting, and perforation of the inferior vena cava;

b. It was designed in such a manner so as to result in a statistically significant incidence of injury to the organs and anatomy; and,

c. It was manufactured in such a manner so that the exterior surface of the DENALI Filter System was inadequately, improperly and inappropriately prepared and/or finished causing the device to weaken and fail.

135. Plaintiff and Plaintiff's health care providers reasonably relied on the superior skill and judgment of Defendants as the designers, researchers and manufacturers of the product, as to whether the DENALI Filter was of merchantable quality and safe and fit for its intended use, and also relied on the implied warranty of merchantability and fitness for the particular use and purpose for which the DENALI Filter was manufactured and sold.

136. Defendants placed the DENALI Filter into the stream of commerce in a defective, unsafe, and unreasonably dangerous condition, and the product was expected to and did reach Plaintiff without substantial change in the condition in which the DENALI Filter was manufactured and sold.

137. Defendants breached their implied warranty because their DENALI Filter was not fit for its intended use and purpose.

138. As a proximate result of Defendants breaching their implied warranties, Plaintiff has suffered and will continue to suffer serious physical injuries, economic loss, loss of enjoyment of life, disability, and other losses, in an amount to be determined at trial.

SIXTH CAUSE OF ACTION
NEGLIGENT MISREPRESENTATION

139. Plaintiff re-alleges and incorporates by reference each and every allegation contained in the foregoing paragraphs as though fully set forth herein.

140. At all times relevant to this cause, and as detailed *supra*, Defendants negligently provided Plaintiff, Plaintiff's health care providers, and the general medical community with false or incorrect information, or omitted or failed to disclose material information concerning the DENALI Filter, including, but not limited to, misrepresentations relating to the following subject areas:

a. The safety of the DENALI Filter;

b. The efficacy of the DENALI Filter;

c. The rate of failure of the DENALI Filter; and

d. The approved uses of the DENALI Filter.

141. The information distributed by Defendants to the public, the medical community and Plaintiff's health care providers was in the form of reports, press

releases, advertising campaigns, labeling materials, print advertisements, commercial media containing material representations, which were false and misleading, and contained omissions and concealment of the truth about the dangers of the use of the DENALI Filter. Defendants made the foregoing misrepresentations knowing that they were false or without reasonable basis. These materials included instructions for use and warning document that was included in the package of the DENALI Filter that was implanted in Plaintiff.

142. Defendants' intent and purpose in making these misrepresentations was to deceive and defraud the public and the medical community, including Plaintiff's health care providers; to gain the confidence of the public and the medical community, including Plaintiff's health care providers; to falsely assure them of the quality of the DENALI Filter and its fitness for use; and to induce the public and the medical community, including Plaintiff's healthcare providers to request, recommend, prescribe, implant, purchase, and continue to use the DENALI Filter.

143. The foregoing representations and omissions by Defendants were in fact false. The DENALI Filter is not safe, fit, and effective for human use in its intended and reasonably foreseeable manner. The use of the DENALI Filter is hazardous to the user's health, and said device has a serious propensity to cause users to suffer serious injuries, including without limitation, the injuries Plaintiff

suffered. Further, the device has a significantly higher rate of failure and injury than do other comparable devices.

144. In reliance upon the false and negligent misrepresentations and omissions made by Defendants, Plaintiff and Plaintiff's health care providers were induced to, and did use the DENALI Filter, thereby causing Plaintiff to sustain severe and permanent personal injuries.

145. Defendants knew and had reason to know that Plaintiff, Plaintiff's health care providers, and the general medical community did not have the ability to determine the true facts intentionally and/or negligently concealed and misrepresented by Defendants, and would not have prescribed and implanted same, if the true facts regarding the device had not been concealed and misrepresented by Defendants.

146. Defendants had sole access to material facts concerning the defective nature of the product and its propensity to cause serious and dangerous side effects in the form of dangerous injuries and damages to persons who are implanted with the DENALI Filter.

147. At the time Defendants failed to disclose and misrepresented the foregoing facts, and at the time Plaintiff used the DENALI Filter, Plaintiff and Plaintiff's health care providers were unaware of said Defendants' negligent misrepresentations and omissions.

148. Plaintiff, Plaintiff's health care providers and general medical community reasonably relied upon misrepresentations and omissions made by Defendants where the concealed and misrepresented facts were critical to understanding the true dangers inherent in the use of the DENALI Filter.

149. Plaintiff and Plaintiff's health care provider's reliance on the foregoing misrepresentations and omissions by Defendants' were the direct and proximate cause of Plaintiff's injuries as described herein.

PUNITIVE DAMAGES ALLEGATIONS

150. Plaintiff re-alleges and incorporates each and every allegation in this Complaint, as if fully set forth herein.

151. Plaintiff is entitled to an award of punitive and exemplary damages based upon Defendants' intentional, willful, knowing, fraudulent, malicious acts, omissions, and conduct, and their complete and total reckless disregard for the public safety and welfare.

152. Defendants had knowledge of, and were in possession of evidence demonstrating that, the DENALI Filter was defective and unreasonably dangerous and had a substantially higher failure rate than did other similar devices on the market. Yet, Defendants failed to:

d. Inform or warn Plaintiff or his health care providers of the dangers;

b. To establish and maintain an adequate quality and post-market surveillance system; and,

c. Recall the DENALI Filter from the market.

153. Defendants acted to serve their own interests and having reasons to know and consciously disregard the substantial risk that their product might kill or significantly harm patients, or significantly injure the rights of others, and consciously pursue a course of conduct knowing that such conduct created a substantial risk of significant harm to other persons.

154. As a direct, proximate, and legal result of Defendants' acts and omissions described herein, Plaintiff has suffered and will continue to suffer serious physical injuries, economic loss, loss of enjoyment of life, disability, and other losses, in an amount to be determined at trial.

PRAYER FOR DAMAGES

WHEREFORE, Plaintiff prays for relief on the entire complaint, as follows:

a. Judgment to be entered against all defendants on all causes of action of this Complaint

b. Reasonable and necessary medical expenses for treatment received in the past and, based upon reasonable medical

probability, the reasonable medical expenses Plaintiff will need in the future;

c. Loss of earning capacity in the past and future; and

d. Punitive damages.

e. Plaintiff be awarded full, fair, and complete Denali for all claims and causes of action relevant to this action;

f. Plaintiff be awarded all appropriate costs, fees, expenses, and pre-judgment and post judgment interest pursuant to the laws of the State of New Jersey as authorized by law on the judgments entered in Plaintiff' behalf; and,

g. Such other relief the court deems just and proper.

Dated: November 27, 2019

Respectfully submitted,

By: */s/ Tayjes Shah*

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